Medical Informatics Academia and Industry: A Symbiotic Relationship that May Assure Survival of Both Through Health Care Reform

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ABSTRACT

There are often clear lines drawn identifying the demilitarized zone between medical informatics academics and industry. Academics were "pure" intellectuals sequestered in ivory towers that effectively shielded them from the realities of the world. Industry has historically focused on creating effective products that produce financial return to the corporation. Both the paradigms of academia and industry are quickly becoming dinosaurs in the era of health care reform where both medical informatics academia and industry are under increasing pressure to develop and prove that medical informatics has a positive impact on health care both in terms of the quality of care as well as cost. Unfortunately, neither academia or industry alone are going to be able to successfully complete this task. The purpose of this paper is to describe such a collaborative effort that has produced a computerized decision support system for the management of mechanical ventilation in patients with the Adult Respiratory Distress Syndrome (ARDS) that is now installed and supported on three different commercial CIS platforms. This collaborative effort has allowed us to successfully mount a large multi-center clinical trial designed to determine efficacy.

INTRODUCTION

It has been our experience that there are often clear lines drawn identifying the demilitarized zone between medical informatics academics and industry. This has been fostered by the tradition that academics were "pure" intellectuals sequestered in ivory towers that effectively shielded them from the realities of the world. It was perfectly acceptable to spend an entire career pursuing a fascinating concept that may never produce any tangible impact on health care. Industry has historically focused on creating effective products that produce financial return to the corporation. The emphasis has been on development of products on short time schedules that customers will buy. There have been no resources for interesting or clever ideas that will not return a profit in the near term. In the past, one was either an academic or industry man and the two only rarely crossed over the "no-man's land" between them. Those that did cross were viewed with suspicion and rarely successfully made the return trip.

From our perspective, both the paradigms of academia and industry are quickly becoming dinosaurs in the era of health care reform where both medical informatics academia and industry are under increasing pressure to develop and prove that medical informatics has a positive impact on health care both in terms of the quality of care as well as cost. The lack of published evidence (1) supporting medical informatics suggests that neither academia or industry alone are going to be able to successfully complete this task.

Our experience indicates that it is extremely difficult for an academic group to develop a medical informatics tool and disseminate it widely. This is essential in order to complete the large scale outcome studies that will be required to document efficacy (1). We are convinced that industry is not able to effectively create robust clinical decision support systems without the intimate involvement of clinicians and clinical environments. These decision support systems have been shown by many to be the key elements of medical informatics that provide an improvement in the quality of patient care while reducing costs (2, 3).

Only collaboration between academia and industry will successfully produce computerized decision support systems and the clinical trials to demonstrate the efficacy of medical informatics in general. The purpose of this paper is to describe such a collaborative effort that has produced a computerized decision support system for the management of mechanical ventilation in patients with the Adult Respiratory Distress Syndrome (ARDS) that is now installed and supported on three different commercial CIS platforms. This collaborative effort has allowed us to successfully mount a large multi-center clinical trial designed to determine efficacy.

BACKGROUND

The Role of Decision Support Systems in Critical Care

Critical care accounts for about 30% of all acute care inpatient costs. The U.S. national cost of ICU care is about $47 billion annually. There are 84,883 ICU beds in the United States (4). The cost of a sophisticated modern ventilator is approximately $20,000. Despite the lack of conclusive evidence and the complexity of ICU care, mechanical ventilation techniques designed to minimize pressure applied

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across the chest are rapidly becoming standard in many hospitals. The complexity and the opportunity for great variation in medical practice is amply demonstrated by the large number of potential causes of decreased oxygenation in the mechanically ventilated patient (5). This complexity has not been balanced by specific rules and executable guidelines for clinical care and for clinical research. Great variation in clinical practice has, in fact, characterized modern critical care. Some of this variation is undoubtedly clinically important.

Protocol Control Of Care

Virtually all clinical trials employ protocols. These protocols include definitions, patient selection criteria, procedural rules, and guidelines, but usually contain non-specific, judgment requiring suggestions like "optimize PEEP" or "maximize antibiotic therapy." While these are useful general statements and concepts, they are not executable instructions (6-10). Computerized protocols eliminate unnecessary variation in clinical care (11), thus standardizing clinical care and imposing control on the clinical care process. This control can be expected to reduce noise introduced by the clinical caregiver and thereby increase the signal-to-noise ratio for ultimate clinical outcomes (12-15). Unaided humans are not capable of providing the persistent commitment to detail and to decision making logic (rules) necessary to effect standardization of care comparable to that achieved by an executable computerized protocol. Since treatments must be applied in a uniform manner to comparable patients before one can evaluate the outcome of a particular medical intervention, this standardization of care is of importance (16).

Dissemination of Decision Support Systems

Computerized decision support systems (12, 13, 17) were developed to control the intensity of care of patients enrolled in a randomized clinical trial in which ARDS patient outcome after extracorporeal support was compared with that after mechanical ventilation alone (18). We developed protocols for controlling continuous positive pressure ventilation, pressure controlled inverse ratio ventilation (19), low frequency positive pressure ventilation-extracorporeal CO2 removal, and continuous positive airway pressure using the LDS Hospital Health Evaluation through Logical Processing (HELP) information system (2, 3). These protocols controlled mechanical ventilation 95% of the time in 72 ARDS patients. 92% of 19,455 computerized protocol instructions were accepted and followed(13). Survival of ARDS patients was four times the expected rate from historical controls (18)

These protocols are now used routinely for ARDS patients in the Shock Trauma/Intermountain Respiratory Intensive Care Unit at the LDS Hospital and have been used for over 50,000 hours in over 150 ARDS patients. While these HELP system protocols are clearly effective and practical at the LDS Hospital (18, 20), widespread community implementation can only be expected if the HELP system protocols are exportable to other centers and if they can be installed in widely distributed CIS products.

METHODS

The primary goal of our clinical trial (AHCPR HS 06594) was to do a multi-center prospective randomized trial of the decision support system for management of mechanical ventilation. A secondary goal of our trial was to demonstrate that a decision support system developed at one clinical site can be effectively transported to and used at a clinical site uninvolved with its development. Power calculations demonstrated that we would need to enroll approximately 400 patients. The combination of our goals, budget and the power calculations led to the following constraints:

1. This must be a multi-center trial.
2. The trial must be conducted using an information system platform independent of the HELP system.
3. The trial must be conducted at clinical trial sites uninvolved in the creation of the decision support system and in no way connected to LDS Hospital and Intermountain Health Care.
4. Resources were not available to buy new hardware and software to instrument every bed for each clinical site.
5. Ideally, the information system would be used for all routine charting isolating the intervention to the decision support system.
6. We did not have the resources to develop an information system, data entry screens and reports.

In view of these constraints the following plan was designed:

1. Use existing commercial CIS systems with a wide installed customer base.
2. Use hospitals that have installed CIS systems for our clinical trial sites.
3. Develop a collaborative effort with each CIS vendor to develop a generic engine for running rule based decision support systems.
4. Implement our decision support system on each vendors CIS using their proprietary engine.
5. Use the existing CIS to store all necessary clinical trial data.
6. Create a central data center capable of downloading clinical trial data from the CIS systems.
7. Provide central support for all clinical trial sites using the decision support system.

Although the concept of a collaborative effort with industry seemed perfectly reasonable, we found in 1991-1992 that there were no commercial critical care CIS systems, other than the HELP system (3M Corp), that had tools capable of running the rules contained in our decision support system. Contacts with most of the large vendors produced fairly uniform negative responses. In general the following were the barriers to a collaborative development:

1. The view that decision support systems, although important, are not what the customer is demanding
2. The perception that nursing careplans and care paths are far more important to marketing and selling systems.
3. Issues of legal liability associated with clinical decision support systems. If a CIS system began to issue instructions about patient care would it become a target of law suits?
4. Issues related to potential FDA regulation. Are clinical decision support systems a medical device? If so, are they regulated by the FDA?

Only Joel Gochberg and his small company, ACT/PC, who marketed a new critical care CIS known as Argus Windows was willing to take a chance on a collaborative effort. Their product is now owned by Microhealth Systems Inc. (West Orange, NJ) who has started a subsidiary known as Clinical Dimensions Inc which markets the new version of the product known as Carepoint. Their approach to the project was to develop a state automaton that executed sets of rules in a predefined sequence. This engine was then provided to us in order to allow us to implement our rules. Several general problems surfaced that required special routines to be developed:

1. The system did not support rules about temporal sequences. These had to be hand coded C routines.
2. A system needed to be developed to record each instruction, the data that was used in the decision making, and a log of the logical elements used.
3. Each clinical site had the ability to create data entry screens using any variable names they chose with any definition of data types. This implied that we had to add data verification and validation routines to the system in order to independently verify all data used for decision making were appropriate. In addition, we had to make the system flexible enough to allow easy mapping of new variable definitions as the system was taken to new clinical sites.

We are deeply indebted to ACT/PC for all of their support in installing this decision support system at two clinical sites; King Drew Medical Center in LA,CA and Hermann Hospital in Houston, TX. This initial experience allowed us to get our clinical trial underway; however, we rapidly realized that we needed to have at least 6-8 clinical trial sites.

In early 1993, in order to expand our clinical trial, we once again approached John Brimm, MD and Emtek (Tempe, AZ) one of the largest vendors of CIS systems for critical care in the world. Dr. Brimm had always been a supporter of our trial and with his help we were successful in soliciting Emtek's agreement to develop a protocol engine capable of running our decision support system. This process illustrated several important points regarding joint development projects between industry and academia:

1. Projects must conform to standard software development guidelines and standards within the corporation. This meant that a software requirements document had to be created detailing exactly what the new product would do and a verification and validation plan established.
2. New software should be integrated into the system and made part of a standard software release. This assures that it is tested during release testing for compatibility and that it is disseminated via normal mechanisms to all clinical sites. Emtek developed the protocol engine and incorporated it in their new v4.1 release of their System 2000.
3. Items 1 and 2 above mean that new software will be developed and implemented in the same time lines as the rest of the software release. This implies that it is not possible to get a short lead time. From concept to software release this process required approximately 1 year. This also implies that any software problems inherent in a new software release also impact the installation of your product.
4. It is essential that any new software be designed to be as independent as possible and any potential faults isolated in order to minimize the impact on the overall information system.
5. Contracts must be developed that clearly indicate what is expected of both parties and what their responsibilities are. These contracts should be as specific as possible and outline all aspects of legal liability and use of the software product.
6. Non-disclosure agreements should be in place to protect both the academician's and industries intellectual property.
7. If possible, regulatory affairs experts should review the project with regards to FDA regulations. Emtek reviewed this project and it was decided that this software could be used, for this particular clinical trial that includes IRB approval and informed consent, without the need to obtain an IDE.
8. Independent software quality assurance programs must be in place within the academic environment to test the combination of the industry supplied rule based engine and the

clinical decision support system rules.

We developed a version of our decision support system rules for the Emtek protocol engine and implemented them between 8/94 and 12/94. We began testing the entire system using detailed scenarios designed to test all logical elements of the system. Nine man months of testing were required to complete the software quality assurance program prior to installation in a clinical site. Emtek released v 4.1 in beta form in March of 1995. We installed our rules on the Emtek system at Harborview Medical Center in Seattle, WA 4/10/95 and began enrolling patients 5/1/95.

RESULTS

In the first 25 patients supported by computerized protocols using the ARGUS windows product at King Drew Medical Center and Hermann Hospital the protocols were intended to be applied (time from randomization to extubation) 9,694 hours. The protocols were suspended for 762 hours (7.3% of total time). Protocols were suspended for other clinical circumstances not encompassed by the rules of the protocols during which time one would normally stop titration of mechanical ventilation (i.e. transport to OR, or CT scanner, surgical procedure in ICU, or unstable hemodynamics). During the 8,932 hours of protocol use (92.7% of total time) there were 11,625 instructions generated. 528 instructions were not followed for the reasons listed in the following table (N is number of instructions, % is percent of instructions that were not followed (528) , %Tot is the percentage of all instructions (11,625)):

Reason Clinician Entered	N	%	%Tot
Clinician Objection	46	8.7	0.40
Other (Usually data is incorrect)	184	34.9	1.58
Hemodynamically Unstable	147	27.8	1.26
Patient Paralyzed	3	0.6	0.03
Patient Transport To Surgery	6	1.0	0.05
Present Data Not Valid	96	18.2	0.83
Software Bug	2	0.4	0.02
Tech. Problem With Equipment	12	2.3	0.10
Tech. Problems With Mech Vent	2	0.4	0.02
Performing an ICU Procedure	24	4.6	0.21
To Verify Sat With Blood Gas	1	0.2	0.01
Transient Problem	5	0.9	0.04
TOTAL	528	100	4.54

DISCUSSION

Computerized protocols have been successfully exported to other clinical centers and used to effectively control clinical decision making. Certain iterative therapies, such as mechanical ventilation, can be considered tasks within a single knowledge domain, and thus would be amenable to computerized protocol control. Protocols are an extension of the common practice of generating guidelines (21) such as critical paths, routine sets of orders, etc., all of which are efforts to standardize care. This use of computerized protocols to help physicians standardize care contrasts with the more common emphasis in medical informatics upon exploring how humans reason, and upon matching medical expert systems products to individual physician preferences (22). Control of the process of medical care is beneficial (23), (24). Published work from the LDS Hospital indicates that computerized protocols have favorable impacts upon hospital pharmacy and infectious disease departments (25), (26), (27). The standardization of therapy that can be achieved with computerized protocols may contribute to national medical policy formulation. Controlled randomized clinical trial outcome data that identifies the therapies that lead to the best possible patient outcome at the lowest cost will likely be made more credible with protocols which standardize therapy. The higher the credibility of results from such trials, the greater the likelihood that they will eventually influence the formulation of medical policy.

SUMMARY

We have successfully established a joint development program between multiple industrial vendors of critical care information systems in order to create a decision support system for management of mechanical ventilation and to widely disseminate it as part of a multi-center randomized clinical trial. This is a powerful demonstration of what can be accomplished through effective collaboration of industry and academia. Neither of us could have done it alone.

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